In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-0030V

Filed: 30 March 2010

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SHARON BRUSTMAKER,	*	
	*	
Petitioner,	*	
	*	
v.	*	**UNPUBLISHED DECISION**[1]
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * *		

Ronald Craig Homer, Esq., Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner; *Linda Sara Renzi, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

RULING ON ENTITLEMENT
BASED UPON THE WRITTEN RECORD

ABELL, Special Master:

On 17 January 2008, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that she suffered Bells Palsy, Polymyalgia Rheumatica, and Guillain-Barré Syndrome, and that such was related to the administration of the Tetanus-Diphtheria vaccination (Td) on 23 June 2006. Petition (Pet.) at 1. As an alleged vaccine-related injury, Petitioner demanded compensation for unreimbursable expenses

[1] This opinion constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Therefore, unless a motion for review of this decision is filed within 30 days after the time given herein to Petitioner to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

for past or future treatment, pain and suffering, and attorney's fees and costs. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

I. PROCEDURAL HISTORY

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. See Petitioner's Exhibits ("Pet. Ex.") 1-21. Respondent filed its Report, pursuant to Rule 4(c), on 29 May 2009, denying compensation. After sincere attempts throughout calendar year 2008 to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 10 October 2008 for a ruling on the written record, and the Court hereby grants that motion.

II. FACTUAL RECORD

Having been born in 1943, Petitioner's medical history is unsurprisingly complex. By early 2006, she was noted to be experiencing hyperglycemia, anemia, and chronic anxiety. Pet. Ex. 3 at 10. She was also a chronic smoker, having smoked cigarettes for about forty years and smoking about one pack per day in 2006. Pet. Ex. 3 at 14. She received the Td vaccination on 23 June 2006 at her doctor's office, at which time she was reportedly hyperglycemic, pale, and had recently lost weight. Pet. Ex. 3 at 8. She returned thence on 5 July 2006, complaining of (asymmetric) hemiparesis on the right side of her body, inability to close her right eye, and was drooling from her right lip, consistent with Bells Palsy. Pet. Ex. 3 at 7. These symptoms had significantly improved by one week later, when her Bells Palsy was described as "secondary to tetanus booster and weight loss." Pet. Ex. 3 at 5. The Bells Palsy eventually resolved entirely. Pet. Ex. 3 at 4; Pet. Ex. 10 at 3.

On 11 September 2006, Petitioner returned to her doctor, complaining of muscle pain and burning in her legs, and a neurological examination revealed a three month history of cervical pain and paresthesias in her lower extremities. Pet. Ex. 3 at 2; Pet. Ex. 10 at 3. Petitioner went to the emergency room on 6 November 2007 for pain on her left side and blood in her urine. Pet. Ex. 9 at 1. At first she was diagnosed with acute renal colic, possibly renal inflammation due to local bacterial infection, and she was ultimately diagnosed with Polymyalgia Rheumatica by a rheumatologist, who believed such condition unrelated to Petitioner's vaccination. Pet. Ex. 9 at 1; Pet. Ex. 6 at 23. No diagnosis of Guillain-Barré Syndrome was ever given by Petitioner's treating physicians, and her symptoms were unilateral at each presentation.

III. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific

injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccines which Petitioner alleges to have caused her condition(s) were the Td vaccine, listed under categories I on the Vaccine Table. None of the conditions complained of by Petitioner are associated with Td on the Vaccine Table. 42 C.F.R. § 100.3(a). Essentially, this relegates Petitioner's claim to an "actual causation" theory of relief, under which Petitioner must prove that such vaccine actually caused the injury(ies) alleged.

Here, the medical records do not support a causative connection between the vaccination administered and the injuries suffered under an actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the Petitioner's claim, a medical opinion must be offered in support. No medical expert opinion report was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

> [A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioner has not filed medical records or offered medical expert testimony to proffer, let alone explain, a "medical theory causally connecting the vaccination [to] the injury." Certainly absent was a detailed analysis of the Record to indicate a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." As such, Petitioner has not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion. There has not been demonstrated to the Court a "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Q.E.D. See Althen, supra*.

In short, Petitioner has not met the burden of proof set forth in the Act.[3] Petitioner has presented none of the evidence required by the Act in the form of corroborative medical records, and failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

IV. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

s/ Richard B. Abell
Richard B. Abell
Special Master

[3] *See Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating "[t]he requirement that [a] petitioner['s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone"); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) ("The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.").